EXHIBIT B

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Valsartan Products Liability Litigation	MDL No. 2875

DEFENDANTS PRINSTON PHARMACEUTICAL INC., SOLCO HEALTHCARE U.S., LLC, AND ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. AND INTERESTED PARTIES HUAHAI U.S., INC., WALGREEN CO., AND THROGGS NECK PHARMACY'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXPAND THE SCOPE OF MDL NO. 2875

Defendants Prinston Pharmaceutical Inc. ("Prinston"), Solco Healthcare U.S., LLC ("Solco"), and Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), and Interested Party Huahai U.S., Inc. ("Huahai") (collectively, the "Prinston Defendants"), together with Interested Parties Walgreen Co. and Throggs Neck Pharmacy (collectively, the "Pharmacy Defendants"), submit this brief in opposition to Plaintiffs' motion to expand the scope of *In re Valsartan Products Liability Litigation*, MDL No. 2875 (the "Valsartan MDL") to include all potentially carcinogenic contaminants in all angiotensin II receptor blockers ("ARBs").[1]

PRELIMINARY STATEMENT

Plaintiffs' application to expand the Valsartan MDL proposes the inclusion of at least five drugs that are not the subject of any action filed in federal or state court, for unknown types of injuries that have not yet been sustained by any plaintiffs, due to nameless "carcinogenic contaminants" that have not been identified in any recall or other regulatory action in connection with Valsartan or any of the other drugs Plaintiffs seek to include in the Valsartan MDL. The unlimited expansion Plaintiffs propose is wholly unsupported by the JPML's practice for

[1] ZHP is a Chinese corporation that manufactures Valsartan and other ARBs, including Losartan and Irbesartan. Huahai and Solco distribute ZHP's Valsartan, Losartan, and Irbesartan in the United States. Prinston is ZHP's FDA liaison.

centralizing matters pursuant to 28 U.S.C. § 1407. The unknown number of drugs, so-called "carcinogenic contaminants," and alleged injuries mean the JPML has no way to determine if there is a common core of facts warranting centralization as to any, some, or all of the drugs, impurities, and injuries for which Plaintiffs seek inclusion in the Valsartan MDL. The JPML ruling would impact unknown numbers of parties that, because of the prospective nature of the application, will not have been afforded the opportunity to be heard. To be sure, far from enhancing efficiencies, the uncertainties about the identity and number of parties, drugs, impurities, and injuries at issue, which would apparently be discovered, if ever, on a rolling, indeterminate basis, would make management by the MDL court a virtual impossibility.

For these reasons, as discussed more fully below, Plaintiffs' application to expand the Valsartan MDL should be denied.

FACTUAL AND PROCEDURAL BACKGROUND

I. FACTUAL BACKGROUND

A. Angiotensin II Receptor Blockers

This MDL involves Valsartan, which is one of eight drugs known as ARBs. ARBs treat hypertension by blocking the body's angiotensin II receptors, preventing the muscles surrounding blood vessels from contracting. *See* MedicineNet, *Angiotensin II Receptor Blockers (ARBs)*, *accessible at https://www.medicinenet.com/angiotensin_ii_receptor_blockers/article.htm*. This is the "mechanism of action" common to all ARBs. *See id.* In addition to Valsartan, the seven other ARBs are Losartan, Irbesartan, Eposartan, Azilsartan, Candesartan, Olmesartan, and Telmisartan. *See* Exhibit A. According to the U.S. Food and Drug Administration's Orange Book, 54 companies are approved to market these ARBs in the United States. *See id.*

The ARB manufacturing process starts with active pharmaceutical ingredient ("API") manufacturers, who use a combination of processes to create Valsartan API. Finished dose

manufacturers purchase Valsartan API from the API manufacturers and combine it with inactive ingredients and other excipients to create a final product with the desired quantity of Valsartan API in a deliverable form. Distributors and wholesalers typically purchase finished Valsartan medications directly from the finished dose manufacturers, in some instances repackage and relabel those products, and sell them to retail or mail-order pharmacies across the country. Repackagers repackage valsartan medications purchased from distributors or wholesalers into smaller dispensable quantities that are sold directly to physicians or retail pharmacies. Finally, retailers then sell finished Valsartan medications directly to patients.

B. FDA Recalls & Alleged Impurities

In July 2018, drug regulators found that the API manufacturing process for Valsartan may have caused some batches to contain trace amounts of N-Nitrosodimethylamine ("NDMA"). On July 13, 2018, the FDA announced a voluntary recall of Valsartan manufactured by several generic pharmaceutical manufacturers, including those manufactured and distributed by the Prinston Defendants. Since then, some Valsartan drugs have also been recalled for potentially containing trace amounts of N-Nitrosodiethylamine ("NDEA"). In December 2018, companies began recalling specific batches of two other ARBs, Losartan and Irbesartan, for potentially containing trace amounts of NDEA. A small number of Losartan batches have also been recalled for potentially containing a third impurity, N-Nitroso-N-Methyl-4-aminobutyric acid ("NMBA").

NDMA, NDEA, and NMBA are all "nitrosamines," which are a potential byproduct of the manufacturing process for Valsartan API. *See* FDA Statement on the Agency's List of Known Nitrosamine-Free Valsartan and ARB Class Medicines (April 4, 2019), *accessible at https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-Valsartan-and-arb-class-medicines-part-agencys* (stating FDA's understanding that nitrosamines "may be generated when specific chemicals and reaction conditions are present in the

manufacturing process of the drug's API"). Nitrosamines are "found in water and foods, including meats, dairy products and vegetables." FDA Statement on the FDA's Ongoing Investigation into Valsartan and ARB Class Impurities (Jan. 25, 2019), *accessible at https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps*. Plaintiffs allege that nitrosamines may be linked to gastrointestinal cancers.

As a result of these recalls, the FDA investigated other drugs in the ARB class. To date, all recalls have been limited to Valsartan, Losartan, or Irbesartan that potentially contained a nitrosamine. *See* FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan), *accessible at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan*. The FDA now maintains a list of ARBs that the agency has determined do not contain nitrosamines. *See* FDA's Assessment of Currently Marketed ARB Drug Products, *accessible at https://www.fda.gov/drugs/drug-safety-and-availability/fdas-assessment-currently-marketed-arb-drug-products*. This list identifies particular batches of Valsartan, Losartan, and Irbesartan, as well as batches of other ARBs, which could presumably serve as substitutes for patients who need an alternative to their current medication. The FDA repeatedly emphasized that until patients speak with their physician they should continue to take their current medication—even if included on the list of recalled drugs—because the risk of discontinuing this medication "greatly outweighs the potential risk of exposure to trace amounts of nitrosamines." *See* Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications (Aug. 28, 2019), *accessible at https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications*.

According to a news article cited by Plaintiffs, *see* JPML ECF 328-1 at 4 & n.7,[2] an online pharmacy has identified the solvent dimethylformamide ("DMF") in some Valsartan, including the brand name version. *See* Anna Edney, *Fourth Carcinogen Discovered in Heart Pills Used by Millions* (Bloomberg, June 18, 2019), *accessible at https://www.bloomberg.com/news/articles/2019-06-18/fourth-carcinogen-discovered-in-heart-pills-used-by-millions.* DMF is not a nitrosamine. DMF is not a potential byproduct of the chemical process which may lead to the formation of nitrosamines during the API manufacturing process. The FDA has not identified DMF as present in any ARBs or announced any recalls related to DMF.

II. PROCEDURAL BACKGROUND

A. Formation of the Valsartan MDL

In October 2018, Plaintiff Robert Kruk moved to centralize all Valsartan-related actions in the District of New Jersey under 28 U.S.C. § 1407. *See* JPML ECF 1. The Panel held a hearing on Kruk's motion in January 2019 and granted his request on February 14, 2019, establishing the Valsartan MDL. *See* JPML ECF 229. The Panel assigned the Valsartan MDL to the Honorable Robert B. Kugler of the United States District Court for the District of New Jersey. *Id.* at 5. The transfer order limited the MDL to actions involving "common factual questions arising out of allegations that plaintiffs purchased or used generic formulations of Valsartan medications containing the nitrosamine impurities NDMA and/or NDEA." *Id.* at 2. To date, at least 140 Valsartan-related actions have been filed in federal courts.

At the time of the January 2019 hearing, only two plaintiffs had filed actions involving Losartan or Irbesartan. Nevertheless, the Panel asked pointed questions about those drugs at that

[2] References to "JPML ECF" refer to documents appearing on the Panel's docket for MDL No. 2875.

conference. *See* JPML ECF 31 at 23–24. Plaintiffs' counsel stated that there would not be many cases because only a small number of Losartan and Irbesartan batches had been recalled. *See id.* The Panel therefore declined to include Losartan and Irbesartan within the MDL, finding the "record on the factual issues involved in those actions" was "not sufficient for the Panel to make such a determination." JPML ECF 229 at 3 n.8.

B. Valsartan MDL Proceedings

The Valsartan MDL currently involves three Master Complaints asserting three theories of liability: economic loss, personal injury, and medical monitoring. *See* D.N.J. ECF 121–123.[3] The Plaintiffs bring these claims against over 45 defendants at every level of the Valsartan supply chain: API manufacturers, finished dose manufacturers, distributors, wholesalers, re-packagers, pharmacies, and FDA liaisons. *See id.* At case management conferences, the Court has indicated that it plans to set different tracks for litigating the Plaintiffs' three Master Complaints.

The number and types of Defendants in the Valsartan MDL make the litigation administratively complex. Because many of the Defendants are direct competitors who keep records in different formats on different systems, the ESI protocol and discovery confidentiality order required careful and prolonged negotiation. The Court and parties have invested substantial energy to understanding and clarifying the roles each Defendant plays in the supply chain. At the very first Case Management Conference, the Court encouraged the parties to devise a mechanism for dismissal, without prejudice, of Defendants that were not involved in the manufacturing process. *See* D.N.J. ECF 77 at 10 (transcript of 3/27/19 Case Management Conference encouraging parties to devise dismissal agreement). This will allow the Court to establish separate discovery

[3] References to "D.N.J. ECF" refer to documents appearing on the District of New Jersey's docket for Civil Action No. 1:19-md-02875.

and litigation tracks for the different levels of the supply chain. The parties started negotiating this dismissal mechanism in March 2019 and are just now finalizing it. *See id.*; *see also* D.N.J. ECF 213 at 4 (summarizing current status).[4]

The number of Defendants has complicated the discovery process as well. To grapple with variations among Defendants and focus on core manufacturing issues, in April 2019 the Court ordered the API and finished dose manufacturer Defendants to produce preliminary discovery containing relevant documents like Abbreviated New Drug Applications ("ANDAs"), Drug Master Files ("DMFs"), and FDA recall communications. *See* D.N.J. ECF 88. In response, the six API and finished dose manufacturing Defendants have produced over 200,000 pages of documents. The Court intended this preliminary discovery, in part, to provide Plaintiffs context for negotiating search terms and custodians, and for shaping formal discovery requests. *See id.* at 1 n.1 ("The purpose of requiring the early production of core discovery without the necessity of a formal document request, is to help identify the genuine issues in dispute and to assist the parties in their effort to timely frame an acceptable ESI protocol."). The Court then set deadlines for Plaintiffs to propose document requests; for Defendants to raise objections; for the parties to meet and confer on the objections; and for the parties to raise all unresolvable disputes with the Court. *See* D.N.J. ECF 141. That process is now underway. By the time the Panel decides this Motion to Expand, the Court will be finalizing the list of formal document requests—just shy of a year after the MDL was established. *See* D.N.J. ECF 200 at 65 (stating court will hear disputes related to scope of document requests at December 2019 case management conference).

[4] Despite the Court's suggestion that the parties negotiate dismissal of all defendants with only minor involvement in the alleged nitrosamine impurities, Plaintiffs have currently excluded certain minor defendants from this dismissal mechanism. Specifically, Plaintiffs have not agreed to dismiss the large retail-pharmacy defendants.

C. Losartan & Irbesartan Actions

Although Losartan and Irbesartan recalls began almost a year ago, only a handful of Plaintiffs have filed actions involving those drugs. To date, just seven actions that involve only Losartan or Irbesartan have been filed in federal courts outside of the MDL. *See* JPML ECF 332. There are also two "combination" actions alleging that the plaintiff ingested both Valsartan and Losartan. *See id.* All but one of these actions were filed in the last two months, and service has not been completed in many of them. Defendants do not know whether Plaintiffs have initiated service on any foreign defendants under the Hague Convention, which can take up to nine months to complete in some countries.[5]

D. The Parties' Coordination of the Few Losartan and Irbesartan Actions as An Alternative to MDL Centralization

All four of the Losartan and Irbesartan economic-loss actions were originally filed in the District of New Jersey and are currently pending before Judge Kugler. *See* JPML ECF 332. Three were assigned to Judge Kugler upon filing.[6] The fourth was reassigned from Judge Wolfson, also

[5] There are also four additional "combination" cases that were improperly filed directly in the Valsartan MDL: *Bettinger v. Zhejiang Huahai Pharmaceutical Co., Ltd.*, No. 1:19-cv-15180 (D.N.J.); *Long v. Zhejiang Huahai Pharmaceutical Co., Ltd.*, No. 1:19-cv-15844 (D.N.J.); *Magee v. Zhejiang Huahai Pharmaceutical Co., Ltd.*, No. 1:19-cv-15858 (D.N.J.); and *Mims v. Zhejiang Huahai Pharmaceutical Co., Ltd.*, 1:19-cv-16589 (D.N.J.). Only Plaintiff Bettinger has reasserted his Losartan-related claim upon filing a personal injury Valsartan Short Form Complaint. The other three plaintiffs have filed Valsartan Short Form Complaints and abandoned their Losartan claims. If the Panel denies Plaintiffs' motion to expand the Valsartan MDL, the Prinston Defendants intend to move to sever and remove any Losartan claims from the MDL for coordination with the four other non-MDL Losartan and Irbesartan actions pending before Judge Kugler.

[6] *Patras v. Torrent Pharmaceuticals, Inc.*, No. 19-cv-11497 (D.N.J.); *Sanders v. Torrent Pharma, Inc.*, No. 19-cv-12745 (D.N.J); and *Roddey v. Camber Pharmaceuticals, Inc.*, No. 19-cv-12763 (D.N.J.).

of the District of New Jersey, to Judge Kugler after the creation of the MDL.[7] In July 2019, Judge Kugler stayed these four actions pending Plaintiffs' plan to apply for expansion of the Valsartan MDL.

ARGUMENT

Plaintiffs ask to expand the Valsartan MDL to include *all* ARBs and *any* potentially carcinogenic contaminant as to *any* cancer. *See* JPML ECF 328 at 1. This request is entirely inconsistent with Panel precedent and is unwarranted given the number of existing actions. Section 1407 allows transfer "[w]hen civil actions involving one or more common questions of fact are pending in different districts" and transfer "will be for the convenience of the parties and witnesses and will promote the just and efficient resolution of such actions." 28 U.S.C. § 1407(a). Neither requirement is met here.

To determine whether transfer is appropriate, the Panel asks whether there is a critical mass of actions that "arise from a common factual core." *In re Blue Cross Blue Shield Antitrust Litig.*, 908 F. Supp. 2d 1373, 1376 (J.P.M.L. 2012); *see also In re M3Power Razor Sys. Mktg. & Sales Practices Litig.*, 398 F. Supp. 2d 1363, 1364 (J.P.M.L. 2005). Centralizing such actions will usually serve the purposes of § 1407 by "eliminat[ing] duplicative discovery" and "conserv[ing] the resources of the parties, their counsel and the judiciary." *In re Blue Cross*, 908 F. Supp. 2d at 1376. The Panel makes this decision by carefully considering *existing* actions, not suggestions from counsel about what might be filed in the future. *See In re Proton-Pump Inhibitor Prods. Liab. Litig.*, 273 F. Supp. 3d 1360, 1362–63 (J.P.M.L. 2017) ("The Panel has been disinclined to take into account the mere possibility of future filings in its centralization calculus."); *In re Lipitor*

[7] *Wineinger v. Solco Healthcare U.S., LLC*, No. 19-cv-01070 (D.N.J.).

(Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig., 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013) (same).

Centralization is only warranted when there are more than "a minimal number of actions…involved." *In re Cal. Wine Inorganic Arsenic Levels Prods. Liab. Litig.*, 109 F. Supp. 3d 1362, 1363 (J.P.M.L. 2010) (citing *In re Transocean Ltd. Sec. Litig. (No. II)*, 753 F. Supp. 2d 1373, 1374 (J.P.M.L. 2010)). "Indeed, centralization under Section 1407 should be the last solution after considered review of all other options," including informal coordination among the parties. *In re Best Buy Co., Cal. Song-Beverly Credit Card Act Litig.*, 804 F. Supp. 2d 1376, 1378 (J.P.M.L. 2011); *see also In re Invokana (Canagliflozin) Prod. Liab. Litig.*, 223 F. Supp. 3d 1345, 1348 (J.P.M.L. 2016) (declining to include two additional drugs in existing MDL when only 21 actions had been filed); *In re Proton-Pump Inhibitor*, 273 F. Supp. 3d at 1362–63 (denying centralization when "just fifteen cases and 24 tag-alongs" had been identified).

Because efficiency and effective case management are the touchstones of § 1407, the Panel disfavors MDLs that include multiple competing defendants and an entire drug class. *See, e.g., In re Fluoroquinolone Prod. Liab. Litig.*, 122 F. Supp. 3d 1378, 1379 (J.P.M.L. 2014) (stating that Panel is "typically…hesitant" to centralize litigation "on an industry-wide basis"); *In re Invokana*, 223 F. Supp. 3d at 1348 (denying request to transfer all actions involving a particular drug on a class-wide basis). Actions that involve different drugs "involve unique product- and defendant-specific issues (such as different product designs, manufacturing processes, regulatory histories, and company documents and witnesses) that will overwhelm the few common issues." *In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012) (denying request to centralize "all actions involving fentanyl patches irrespective of manufacturer"). Centralization of actions involving an entire class of drug—"regardless of the manufacturer"—is

appropriate only if the actions would "share factual questions regarding general causation (in particular, *the biological mechanism of the alleged injury*), the background science, and common regulatory issues." *In re Fluoroquinolone*, 122 F. Supp. 3d at 1379 (emphasis added); *see also In re Viagra (Sildenafil Citrate) Prod. Liab. Litig.*, 224 F. Supp. 3d 1330, 1332 (J.P.M.L. 2016). Furthermore, a "multi-defendant MDL may prolong pretrial proceedings, because of, *inter alia*, the possible need for separate discovery and motion tracks, as well as the need for additional bellwether trials." *In re Invokana*, 223 F. Supp. 3d at 1348.[8]

In light of these clear and well-established principles, Plaintiffs' motion to expand the Valsartan MDL is wholly inappropriate. There is no support for Plaintiffs' request to include the entire class of ARBs, especially given that only three of them are the subject of federal court actions, and Plaintiffs would have the expansion as to those ARBs cover an unlimited and unknown set of so-called impurities and injuries allegedly caused thereby, all on an as yet un-filed basis. Moreover, the number of cases concerning those drugs—nine—is no more sufficient a number than the two that were on file in January to warrant their inclusion, even as to NDMA, NDEA and NMBA. The parties have successfully coordinated the small number of Losartan and Irbesartan cases with the MDL.

I. THE VALSARTAN MDL SHOULD NOT BE EXPANDED TO INCLUDE ALL ARBS AND ANY CARCINOGENIC CONTAMINANT.

The Panel should deny Plaintiffs' request to expand the Valsartan MDL to include *any* potentially carcinogenic contaminant in *any* ARB. Section 1407 transfer is limited to similar

[8] Plaintiffs' reliance on the generic-drug price-fixing MDL is misplaced. *See* JPML ECF 328-1 at 5. The Panel centralized those actions because they alleged a common price-fixing conspiracy. *See In re Generic Digoxin and Doxycycline Antitrust Litig.*, 222 F. Supp. 3d 1341, 1343 (J.P.M.L. 2017). That MDL therefore does not involve drug-specific questions about the drugs' manufacturing process, regulatory history, or biological performance. *See id.* at 1343–44.

actions "*pending in different districts*." 28 U.S.C. § 1407(a) (emphasis added). There are no existing actions to support this request to expand the MDL beyond the alleged presence of nitrosamines in the three ARBs that have been recalled. As Plaintiffs acknowledge, the ARB recalls have been limited to a single type of impurity (nitrosamines) in three specific ARBs (Valsartan, Losartan, and Irbesartan). *See* JPML ECF 328-1 at 1. The FDA has not identified any other impurities and has confirmed that batches of other ARBs are safe to consume.[9] Plaintiffs' effort to expand the MDL on the basis of hypothetical future actions should not be rewarded. *See, e.g., Proton-Pump*, 273 F. Supp. 3d at 1362–63 (refusing "to take into account the mere possibility of future filings in [the] centralization calculus"); *In re Lipitor*, 959 F. Supp. 2d at 1376 (same).

Without the benefit of existing complaints, the Panel cannot determine whether the hypothetical actions would share a common factual core with the Valsartan MDL such that centralization would promote efficiency. Plaintiffs attempt to cabin their proposed scope by limiting the expanded MDL to *carcinogenic* contaminants, *see* JPML ECF 328 at 1, but a variety of substances can cause different types of cancer by interacting with the body in different ways. Plaintiffs' one example of a potential additional contaminant, DMF, is instructive. *See* JPML ECF 328-1 at 4. The FDA has not recalled any ARBs for containing DMF, and no lawsuits alleging

[9] The FDA has also repeatedly advised consumers not to discontinue taking their recalled Valsartan without first speaking with a doctor about whether an alternative medication would be more appropriate treatment. *See, e.g.,* FDA Statement on FDA's Ongoing Investigation (Jan. 15, 2019), *accessible at https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps* ("We remind patients taking these medications or any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option."); Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications (Aug. 28, 2019), *accessible at https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications* ("We continue to encourage patients talk to a health care professional if they have questions about their medicine, as the risks of stopping taking an ARB product for treating high blood pressure and heart failure greatly outweighs the potential risk of exposure to trace amounts of nitrosamines.").

DMF contamination currently exist. DMF is not a nitrosamine. Therefore, a hypothetical DMF action would not share general causation questions with the Valsartan MDL. And according to Plaintiffs' news article, DMF is a solvent with no known explanation for why it would be present in certain drugs, whereas nitrosamines are a potential byproduct of a specific series of chemical reactions which may occur during the API manufacturing process. *See* Anna Edney, *Fourth Carcinogen Discovered in Heart Pills Used by Millions* (Bloomberg, June 18, 2019), *accessible at https://www.bloomberg.com/news/articles/2019-06-18/fourth-carcinogen-discovered-in-heart-pills-used-by-millions; see also* FDA Statement on the Agency's List of Known Nitrosamine-Free Valsartan and ARB Class Medicines (April 4, 2019), *accessible at https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-Valsartan-and-arb-class-medicines-part-agencys* (stating FDA's understanding that nitrosamines "may be generated when specific chemicals and reaction conditions are present in the manufacturing process of the drug's API"). In short, DMF actions would involve different manufacturers with different regulatory histories and manufacturing processes; and a different alleged impurity that results from a different issue with the manufacturing process. If any DMF actions are ever filed, transfer would not be appropriate under § 1407.

Furthermore, adding *all* ARBs would make this already-complex MDL impossible to manage efficiently. The Valsartan MDL already involves three theories of injury asserted against 45+ defendants from every level of the Valsartan supply chain. Coordinating all preliminary issues has been an extensive and exhausting undertaking for the parties and Court alike. Opening the MDL to seven additional drugs would add *even more* parties and issues to this litigation. The FDA's Orange Book identifies 11 companies authorized to market the Eposartan, Olmesartan, Azilsartan, Candesartan, or Telmisartan, but not authorized for Valsartan, Losartan, or Irbesartan.

See Exhibit A. And the FDA's Orange Book does not account for companies that operate further down the supply chain—such as distributors, wholesalers, or repackagers. Expanding the MDL to include *any* ARB would therefore add countless additional defendants to an MDL that already has too many, frustrating the Court's dedication to winnowing the parties to a manageable number.

Moreover, the Plaintiffs propose an amorphous and forward-looking definition that would allow them to file actions alleging *an unlimited number* of contaminants. This opens the door for Plaintiffs to change the MDL's boundaries significantly and unexpectedly, including years down the road. Current Plaintiffs may intend to include only additional actions based on the known impurities already identified by the FDA, but no constraint exists to prevent future Plaintiff's counsel from expanding the MDL in any number of conceivable ways. Such a broad and ever-changing MDL would be wholly disruptive to the efficient resolution of these cases, and would frustrate the Court's dedication to carefully defining the central issues and appropriately tailoring discovery. An unbounded MDL involving *all* ARBs and yet-unidentified contaminants that likely will not share a common factual core would not "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a).

II. THE VALSARTAN MDL SHOULD NOT BE EXPANDED TO INCLUDE LOSARTAN AND IRBESARTAN.

In February 2019, the Panel found that the factual record did not support transfer of the Losartan or Irbesartan actions to the MDL. *See* JPML ECF 229 at 3 n.8. That factual record has not materially changed. In the seven months that have passed, Plaintiffs have filed only seven more cases involving these ARBs. For the same reasons the Panel denied centralization seven months ago, the Panel should decline to expand the Valsartan MDL today.

There are only five Losartan actions and two "combination" cases alleging that plaintiff ingested both Losartan and Valsartan. *See* JPML ECF 332. That is an insufficient number of cases

to require § 1407 transfer rather than informal coordination among the parties. *See In re Invokana*, 223 F. Supp. 3d at 1348 (finding 21 actions a "relatively small number" that did not warrant "class-wide centralization"). Informal coordination of these actions is "both practicable and preferable" because: (1) there are only a few cases, (2) many are pending in the same court before the same judge, who is also overseeing the Valsartan MDL, and (3) defendants are represented by "national counsel coordinating [their] response to this litigation." *In re Mirena IUD Levonorgestrel-Related Prods. Liab. Litig.*, 38 F. Supp. 3d 1380, 1381 (J.P.M.L. 2014) (denying transfer); *In re Chilean Nitrate Prods. Liab. Litig.*, 787 F. Supp. 2d 1347, 1347 (J.P.M.L. 2011) (same). Also, the Prinston Defendants are ready and willing to work with Plaintiffs' counsel to coordinate these actions. *See In re Mirena IUD*, 38 F. Supp. 3d at 1381 (denying transfer when defendant was "ready and willing" to coordinate informally); *In re Lipitor*, 959 F. Supp. 2d at 1376 (same).

Furthermore, adding Losartan would complicate the already complex Valsartan MDL with defendant- and drug-specific questions. Although Losartan, like Valsartan, is an ARB, "they are not identical" drugs. *In re Proton-Pump Inhibitor*, 273 F. Supp. 3d at 1362 (denying class-wide transfer). Losartan actions will involve distinct questions regarding "development, testing, and marketing history." *Id.* This is especially true because the allegations in these cases center on a potential byproduct of the API manufacturing process, not on a side-effect of the mechanism of action common to all ARBs. The Losartan actions will therefore involve questions related to the manufacturing process and design for Losartan specifically, which is distinct from the manufacturing process for Valsartan. *Compare In re Fluoroquinolone*, 122 F. Supp. 3d at 1379 (centralizing actions involving multiple injectable fluoroquinolone drugs when alleged injury was caused by "the biological mechanism" of the drugs) *with In re Viagra*, 261 F. Supp. 3d at 1332 (centralizing Viagra and Cialis actions when injury allegedly caused by "the same mechanism of

action" common to both drugs). And to the extent there are common causation questions related to the effect of nitrosamines on human health, counsel can coordinate informally on that narrow issue. Where, as here, the Court has already established multiple litigation tracks for the theories of Valsartan injury—and multiple litigation tracks for the different members of the supply chain—informal coordination of a handful of actions is preferable to injecting drug-specific questions into the Valsartan MDL.

At the very least, the Valsartan MDL should not be expanded to include Irbesartan. Only two Irbesartan actions have been filed. *See* JPML ECF 332. Because only 45 lots of Irbesartan have been recalled, it is unlikely that many more cases, if any, will arise. *See* JPML ECF 328-1 at 3 (describing lots of Irbesartan recalled). The Prinston Defendants are also willing to work with Plaintiffs' counsel to coordinate these two actions informally. There is no reason to complicate the Valsartan MDL with Irbesartan-specific questions given the small number of cases.

III. THE VALSARTAN MDL CAPTION SHOULD NOT BE CHANGED TO INCLUDE THE WORD CONTAMINATION.

The Panel should reject Plaintiffs' renewed attempt to include the word "contamination" in the MDL caption. The Panel has already rejected this request once. When Plaintiff Kruk moved to centralize all Valsartan actions, he proposed the caption "In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination Litigation." *See* JPML ECF 1. Defendants opposed this caption on the grounds that the word "contamination" was both incorrect and prejudicial. *See* JPML ECF 80 at 9. The Panel declined to adopt Plaintiffs' caption in favor of a neutral and accurate description: "In re Valsartan Products Liability Litigation." *See* JPML ECF 229 at 1.

"Contamination" is a term of art when used in the context of describing a pharmaceutical. Whether Valsartan, Losartan, or Irbesartan were "contaminated" with nitrosamines, or not, must

await discovery and the admissible opinions of expert witnesses as determined by the trial court. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Such a conclusory naming of the proposed consolidated proceedings by Plaintiffs likewise injects potential and unacceptable bias into these proceedings implicitly designed to shape factfinder perceptions and attitudes against the Defendants. This Panel should reject Plaintiffs second attempt at inappropriate naming.

CONCLUSION

For the foregoing reasons, the Prinston Defendants and Pharmacy Defendants oppose Plaintiffs' motion to expand the Valsartan MDL to "include all cases concerning all ARB drugs and carcinogenic contaminants." JPML ECF 328-1 at 8.

Dated: September 19, 2019

Respectfully submitted,

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EXHIBIT A

TABLE OF ANGIOTENSIN RECEPTOR BLOCKERS
(Source: FDA Orange Book)
(As of August 30, 2019)

Drug Name	**Manufacturers and/or ANDA/NDA holders**
Valsartan	Alembic Pharmaceuticals Ltd. Alkem Laboratories, Ltd. Allergan Sales, LLC Amneal Pharmaceuticals of New York, LLC Apotex, Inc. Aurobindo Pharma, Ltd. Carmel Biosciences, Inc. Hetero Labs, Ltd. Invagen Pharmaceuticals, Inc. Ivax Pharmaceuticals, Inc. Jubilant Generics, Ltd. Lupin, Ltd. MacLeods Pharmaceuticals, Ltd. Mylan Pharmaceuticals, Inc. Novartis Pharmaceuticals Corp. Novel Laboratories, Inc. OHM Laboratories, Inc. Par Pharmaceutical, Inc. Prinston Pharmaceutical Inc. Square Pharmaceuticals, Ltd. Teva Pharmaceuticals USA Torrent Pharmaceuticals, Ltd. Unichem Laboratories, Ltd. Watson Laboratories, Inc. Zydus Pharmaceuticals USA, Inc.
Irbesartan	Ajanta Pharma, Ltd. Alembic Pharmaceuticals, Ltd. Amneal Pharmaceuticals, Inc. Apotex, Inc. Atlas Pharmaceuticals, LLC Aurobindo Pharma, Ltd. Chartwell Molecular Holdings, LLC Dr. Reddy's Laboratories, Ltd. Hetero Labs, Ltd. Hisun Pharmaceutical Hangzhou Co., Ltd. Jubilant Generics, Ltd. Lupin, Ltd. MacLeods Pharmaceuticals, Ltd. Mylan Pharmaceuticals, Inc.

	Neopharma, Inc. Prinston Pharmaceutical Inc. Sandoz, Inc. Sanofi Aventis US, LLC Sciegen Pharmaceuticals, Inc. Teva Pharmaceuticals USA, Inc. Unichem Laboratories, Ltd. Watson Laboratories, Inc. West-Ward Pharmaceuticals International, Ltd. Zydus Pharmaceuticals USA, Inc.
Losartan	Alembic Pharmaceuticals, Ltd. Apotex Corp. Aurobindo Pharma, Ltd. Cadista Pharmaceuticals, Ltd. Hetero Labs, Ltd. IPCA Laboratories, Ltd. Lupin, Ltd. MacLeods Pharmaceuticals, Ltd. Merck Sharp and Dohme Corp. Micro Labs, Ltd. Mylan Pharmaceuticals, Inc. Prinston Pharmaceutical Inc. Sandoz, Inc. Strides Pharma Global PTE, Ltd. Teva Pharmaceuticals USA, Inc. Torrent Pharmaceuticals, Ltd. Unichem Laboratories, Ltd. Upshaw Smith Laboratories, LLC Watson Laboratories, Inc. West-Ward Pharmaceuticals International, Ltd. Zydus Pharmaceuticals USA, Inc.
Eposartan	Mylan Pharmaceuticals, Inc. Abbvie, Inc.
Olmesartan	Accord Healthcare, Inc. Ajanta Pharma, Ltd. Alembic Pharmaceuticals, Ltd. Alkem Laboratories, Ltd. Aurobindo Pharma, Inc. Daiichi Sankyo, Inc. Glenmark Pharmaceuticals, Ltd. Jubilant Generics, Ltd. Lupin, Ltd.

	MacLeods Pharmaceuticals, Ltd. Micro Labs, Ltd. Par Pharmaceuticals, Inc. Prinston Pharmaceutical Inc. Qilu Pharmaceutical Co., Inc. Sciegen Pharmaceuticals, Inc. Sunshine Lake Pharma Co., Ltd. Teva Pharmaceuticals USA, Inc. Torrent Pharmaceuticals, Ltd. Umedica Laboratories Private, Ltd. Zydus Pharmaceuticals USA, Inc.
Azilsartan	Arbor Pharmaceuticals, LLC
Candesartan	ANI Pharmaceuticals, Inc. Alembic Pharmaceuticals, Ltd. Apotex, Inc. Dr. Reddy's Laboratories, Ltd. MacLeods Pharmaceuticals, Ltd. Mylan Pharmaceuticals, Inc. Prinston Laboratories Inc. Zydus Pharmaceuticals USA, Inc.
Telmisartan	Alembic Pharmaceuticals, Ltd. Amneal Pharmaceuticals, Inc. Aurobindo Pharma, Inc. Boehringer-Ingelheim Pharmaceuticals, Inc. Cadila Pharmaceuticals, Ltd. Cipla, Ltd. Glenmark Pharmaceuticals, Ltd. Hetero Labs, Ltd. Hisun Pharmaceutical Hangzhou Co., Ltd. Inventia Healthcare Private, Ltd. Jubilant Generics, Ltd. Lupin, Ltd. MacLeods Pharmaceuticals, Ltd. Micro Labs, Ltd. Mylan Pharmaceuticals, Inc. Prinston Pharmaceutical Inc. Sandoz, Inc. Zydus Pharmaceuticals USA, Inc.

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: Valsartan Products Liability Litigation	**MDL No. 2875**

CERTIFICATE OF SERVICE

In compliance with Rule 4.1(a), I, Seth A. Goldberg, hereby certify that on September 19, 2019 I served the foregoing Response in Opposition to Plaintiffs' Motion to Expand the Scope of MDL No. 2875 via the CM/ECF system on all counsel of record or via U.S. Mail as follows:

***Wineinger v. Solco Healthcare U.S., LLC*, No. 1:19-cv-01070 (D.N.J)**	
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***Bennett v. Zhejiang Huahai Pharmaceutical Co., Ltd.*, No. 2:19-cv-02418 (W.D. Tenn.)**	
Counsel for Plaintiffs Myra Bennett and James Jongewaard: David M. McMullan, Jr. Barrett Law Group, P.A. P.O. Box 927 404 Court Square Lexinton, MS 39095 Phone: (662) 834-2488 Email: dmcmullan@barrettlawgroup.com	
***Patras v. Torrent Pharmaceuticals, Inc.*, No. 1:19-cv-11497 (D.N.J.)**	
Counsel for Plaintiff Argyre Patras: Rosalee B.C. Thomas Finkelstein Thompson LLP 1077 30th Street, NW Suite 150	*Counsel for Defendants Torrent Pharmaceuticals, Ltd. and Torrent Pharma, Inc.:* Eric I. Abraham Yevgenia Shtilman Kleiner

Washington, D.C. 20007 Phone: (202) 337-8000 Email: rbcthomas@finkelsteinthompson.com	Hill Wallack, LLP 21 Roszel Road Princeton, NJ 08543 Phone: (609) 924-0808 Email: ehart@duanemorris.com *Counsel for Defendant Hetero USA, Inc.:* Janet L. Poletto Hardin, Kundla, Mc Keon, Poletto & Polifroni, PC 673 Morris Avenue P.O. Box 730 Springfield, NJ 07081 Phone: (973) 912-5222 Email: jpoletto@hkmpp.com *Via U.S. Mail only to:* Hetero Drugs, Ltd. 7-2-A2 Hetero Corporate Industrial Estate Sanathnagar Hyderabad, Telangana 500018
***Sanders v. Torrent Pharma, Inc.*, No. 1:19-cv-12745 (D.N.J.)**	
Counsel for Plaintiffs Ira Sanders, Joseph Cummings, Solomon Zeller, Rosa Burton and Damita Owens: Andrew J. Obergfell Bursor & Fisher PA 888 Seventh Avenue New York, NY 10106 Phone: (646) 837-7129 Email: aobergfell@bursor.com	*Counsel for Defendant Torrent Pharma, Inc.:* Christina L. Saveriano 1 Valley Lane Mullica Hill, NJ 08062 Phone: (856) 366-5637 Email: christyoberhaus@hotmail.com Devora W. Allon Kirkland & Ellis LLP 601 Lexington Ave. New York, NY 10022 Phone: (212) 446-5967 Email: devora.allon@kirkland.com
***Roddey v. Camber Pharmaceuticals, Inc.*, No. 1:19-cv-12763 (D.N.J.)**	
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New York, NY 10106 Phone: (646) 837-7129 Email: aobergfell@bursor.com	Princeton, NJ 08540 Phone: (609) 514-5978 Email: mgeist@reedsmith.com *Counsel for Defendant Hetero USA, Inc.:* Janet L. Poletto Hardin, Kundla, Mc Keon, Poletto & Polifroni, PC 673 Morris Avenue P.O. Box 730 Springfield, NJ 07081 Phone: (973) 912-5222 Email: jpoletto@hkmpp.com Attorney for Defendant Hetero USA, Inc. *Counsel for Defendant Legacy Pharmaceutical Packaging, LLC:* Jason A. Nagi Polsinelli PC 600 Third Avenue, 42nd Floor New York, NY 10016 Phone: (212) 684-0199 Email: jnagi@polsinelli
***Noe v. Hetero Labs Ltd.*, No. 4:19-cv-00054 (W.D. Ky.)**	
Counsel for Plaintiff Henry Noe: Alex C. Davis Jones Ward PLC 1205 E. Washington Street Suite 111 Louisville, KY 40206 Phone: (502) 882-6000 Email: alex@jonesward.com Daniel A. Nigh Levin Papantonio Thomas Mitchell Rafferty & Proctor PA 316 S. Baylen Street Suite 600 Pensacola, FL 32502 Phone: (850) 435-7013 Email: dnigh@levinlaw.com	*Counsel for Defendant Torrent Pharmaceuticals, Ltd. and Torrent Pharma, Inc.:* Devora W. Allon Kirkland & Ellis LLP 601 Lexington Ave. New York, NY 10022 Phone: (212) 446-5967 Email: devora.allon@kirkland.com *Counsel for Defendant Hetero USA, Inc.:* Janet L. Poletto Hardin, Kundla, Mc Keon, Poletto & Polifroni, PC 673 Morris Avenue P.O. Box 730 Springfield, NJ 07081 Phone: (973) 912-5222 Email: jpoletto@hkmpp.com

	Via U.S. Mail Only: Hetero Labs, Ltd. Hetero Drugs, Ltd. 7-2-A2 Hetero Corporate Industrial Estate Sanathnagar Hyderabad, Telangana 500018 Camber Pharmaceuticals, Inc. 1031 Centennial Avenue, Piscataway, NJ 08854
***Estate of Larry Brock v. Teva Pharmaceutical Industries Ltd.*, No. 4:19-cv-00538 (E.D. Ark.)**	
Counsel for Plaintiff Estate of Larry Brock: Alyson Oliver Oliver Group PC 1647 West Big Beaver Road Troy, MI 48084 Phone: (248) 327-6556 Email: notifications@oliverlawgroup.com	*Via U.S. Mail Only:* Golden State Medical Supply, Inc. 200 Linden Avenue, Suite 100 Auburn, CA 95603 Teva Pharmaceuticals Industries, Ltd 5 Basel Street Petach Tikva 49131, Israel Teva Pharmaceuticals USA, Inc. 400 Interpace Parkway Parsippany, New Jersey 07054
***Thomas v. Hetero Drugs Ltd.*, No. 6:19-cv-01290 (N.D. Ala.)**	
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	1250 North Lakeview Ave. Unit O Anaheim, CA 92807 Camber Pharmaceuticals, Inc. 1031 Centennial Avenue, Piscataway, NJ 08854
***Branham v. Hetero Drugs Ltd.*, No. 3:19-cv-00265 (E.D. Tenn.)**	
Counsel for Plaintiff Norma Branham: Marlene J. Goldenberg Goldenberg Law, PLLC 800 LaSalle Avenue Suite 2150 Minneapolis, MN 55402 Phone: (612) 436-5028 Email: aohara@goldenberglaw.com Andrea T. McKellar McKellar Hyde PLC 4235 Hillsboro Pike Suite 300 Nashville, TN 37215 Phone: (615) 855-9863 Email: amckellar@mckellarhyde.com	*Counsel for Defendant Hetero USA, Inc.:* Janet L. Poletto Hardin, Kundla, Mc Keon, Poletto & Polifroni, PC 673 Morris Avenue P.O. Box 730 Springfield, NJ 07081 Phone: (973) 912-5222 Email: jpoletto@hkmpp.com *Counsel for Torrent Pharmaceuticals, Ltd. and Torrent Pharma, Inc.:* Devora W. Allon Kirkland & Ellis LLP 601 Lexington Ave. New York, NY 10022 Phone: (212) 446-5967 Email: devora.allon@kirkland.com *Via U.S. Mail Only:* Preferred Pharmaceuticals, Inc 1250 North Lakeview Ave. Unit O Anaheim, CA 92807 Camber Pharmaceuticals, Inc. 1031 Centennial Avenue, Piscataway, NJ 08854 The Kroger Co. 1014 Vine Street Cincinnati, OH 45202

/s/ Seth A. Goldberg
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